

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitution for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number      09/724,685	
<i>(Use as many sheets as necessary)</i>				Filing Date                11-28-2000	
				First Named Inventor     Steven G. Reed	
				Art Unit                    1645	
				Examiner Name           Rodney P. Swartz	
Sheet	20	of	32	Attorney Docket Number    GSK006C13/CRX411C13	

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet		21	of	32	<b>Complete if Known</b>	
					<b>Application Number</b>	09/724,685
					<b>Filing Date</b>	11-28-2000
					<b>First Named Inventor</b>	Steven G. Reed
					<b>Art Unit</b>	1645
					<b>Examiner Name</b>	Rodney P. Swartz
					<b>Attorney Docket Number</b>	GSK006C13/CRX411C13

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	290	ROSENFELD, et al., "Adenovirus-Mediated Transfere of a Recombinant Alpha-1 Antitrypsin Gene to Lung Epithelium in Vivo," Science 252:431-434 (1991)	
	291	ROSSOLINI, et al., "Use of deoxynosine-containing primers versus degenerate primers," Mol. Cell. Probes 8:91-96 (1994)	
	292	SATO, et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization," Science 273:352 (1996)	
	293	SCHARF, et al., "Heat Stress Promoters and Transcription Factors," Results Probl. Cell Differ. 20:125-162 (1994)	
	294	SINGH, et al., "In Vitro Characterization of T Cells from Mycobacterium W-Vaccinated Mice," Infection and Immunity 60(1):257-263 (1992)	
	295	SINHA, et al., "Immunological properties of a 30 Kda secretory protein of Mycobacterium tuberculosis H37RA," Vaccine 15(6-7): 689-99 (1997)	
	296	SIMONNEY, et al., "Analysis of the immunological humoral response to Mycobacterium tuberculosis glycolipid antigens (DAT, PGLTb1) for diagnosis of tuberculosis in HIV-seropositive and seronegative patients," Eur. J. of Clin. Microbiology and Infectious Disease 14(10):883-891 (1995)	
	297	SKEIKY, et al., "LeIF: a recombinant leishmania protein that induces an IL-12 mediated Th cytokine profile," J. of Immunology 161: 6171-79 (1998)	
	298	SKEIKY, et al., "Differential immune responses and protective efficacy induced by components of a tuberculosis polyprotein vaccine, Mtb72F, delivered as naked DNA or recombinant protein," J. of Immunology 172(12):7618-28 (2004)	
	299	SKORKO-GLONEK, "Comparison of the structure of wild-type HtrA heat shock protease and mutant HtrA proteins. A Fourier transform infrared spectroscopic study," JBC 270(19): 11140-11146 (1995)	

<b>Examiner Signature</b>		<b>Date Considered</b>	
---------------------------	--	------------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

<b>Application Number</b>	09/724,685
<b>Filing Date</b>	11-28-2000
<b>First Named Inventor</b>	Steven G. Reed
<b>Art Unit</b>	1645
<b>Examiner Name</b>	Rodney P. Swartz
<b>Attorney Docket Number</b>	GSK006C13/CRX411C13

Sheet 22 of 32

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	300	SKUCE, et al., "Discrimination of M. tuberculosis complex bacterial using novel VNTR-PCR targets," Microbiology 148(2):519-28 (2002)	
	301	STOUTE, et al., "A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine Against Plasmodium Falciparum Malaria," New Engl. J. Med. 336:86-91 (1997)	
	302	TIMMERMAN and LEVY, "Dendritic Cell Vaccines for Cancer Immunotherapy," Ann. Rev. Med 50: 507-529 (1999)	
	303	TRIGLIA, et al., "A Procedure for In Vitro Amplification of DNA Sequences that Lie Outside the Boundaries of Known Sequences," Nucl. Acids Res. 16:8186 (1988)	
	304	TSENOVA, et al., "Evaluation of the Mtb72F Polypeptide Vaccine in a Rabbit Model," Infection and Immunity 74(4):2922-401 (2006)	
	305	ULMER, et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," Science 259:1745-1749 (1993)	
	306	VAN PITTIUS, et al., "Evolution and expansion of the M. tuberculosis PE and PPE multigene families and their association with the duplication of the ESAT-6 (esx) gene cluster regions," BML Evolutionary Biology 6(1):95 (2006)	
	307	VEKEMANS et al., "Immune Responses to Mycobacterial Antigens in the Gambian Population," Infection and Immunity 72(1):381-88 (2004)	
	308	VON ESCHEN, et al., "The candidate tuberculosis vaccine Mtb72F/AS02A," Human Vaccines 5(7):475-82 (2009)	
	309	VERBON, et al., "The 14,000-Molecular-Weight Antigen of Mycobacterium tuberculosis Is Related to the Alpha-Crystallin Family of Low-Molecular-Weight Heat Shock Proteins," J. of Bacteriology 174(4):1352-1359 (1992)	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<b>Application Number</b>	09/724,685
		<b>Filing Date</b>	11-28-2000
		<b>First Named Inventor</b>	Steven G. Reed
		<b>Art Unit</b>	1645
		<b>Examiner Name</b>	Rodney P. Swartz
<b>(Use as many sheets as necessary)</b>	<b>Attorney Docket Number</b>	GSK006C13/CRX411C13	
Sheet	23	of	32

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	310	VORDEMEIER, et al., "Synthetic delivery system for tuberculosis vaccines: immunological evaluation of the M. tuberculosis 38 kDa protein entrapped in biodegradable PLG microparticles," Vaccine 13(16):1576-1582 (1995)	
	311	WALLIS, et al., "Identification of Antigens of Mycobacterium tuberculosis Using Human Monoclonal Antibodies," J. Clin. Invest. 84:214-219 (1989)	
	312	WANG, et al., "Tuberculosis Vaccines: Past, Present and Future," Expert Rev. Vaccines 1(3):341-54 (2002)	
	313	WANG, et al., "A novel method for increasing the expression level of recombinant proteins," Protein Expression and Purification 30(1):124-133 (2003)	
	314	WEBB, et al., "Molecular Cloning, Expression and Immunogenicity of MTB12," Infection & Immunity 66(9):4208-4214 (1998)	
	315	WIEGESHAUS, et al., "Evaluation of the protective potency of new tuberculosis vaccines," Reviews of Infectious Diseases 11(Suppl. 2):S484-S490 (1989)	
	316	WIGLER, et al., "Transformation of mammalian cells with an amplifiable dominant-acting gene," PNAS USA 77:3567-70 (1980)	
	318	WIKER and HARBOE, "The Antigen 85 Complex: a Major Secretion Product of Mycobacterium tuberculosis," Microbiological Reviews 56(4):648-661 (1992)	
	319	WINTER, "The Expression of Heat Shock Proteins and Cognate Genes During Plant Development," Results Probl. Cell Differ. 17: 85-105 (1991)	
	320	ZIMMERMAN, et al. "Immunization with peptide heteroconjugates primes a T helper cell type 1-associated antibody (IgG2a) response that recognizes the native epitope on the 38-kDa protein of Mycobacterium tuberculosis," Vaccine Res. 5(2):103-118 (1996)	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			<b>Application Number</b>	09/724,685	
			<b>Filing Date</b>	11-28-2000	
			<b>First Named Inventor</b>	Steven G. Reed	
			<b>Art Unit</b>	1645	
			<b>Examiner Name</b>	Rodney P. Swartz	
<b>Sheet</b>	24	of	32	<b>Attorney Docket Number</b>	GSK006C13/CRX411C13

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	321	ZITVOGEL, et al., "Eradication of established murine tumors using a novel cell-free vaccine: dendritic cell-derived exosomes," Nature Med. 4:594-600 (1998)		
	322	Seq_NCBI _AL021930.1, 2 pages		
	323	Seq_NCBI _AL021930, 17 pages		
	324	Seq_Accession No. O05907, Database:stremb119, publicly available Jul. 1, 1997		
	325	Seq_Accession No. O05908, Database:stremb119, publicly available Jul. 1, 1997		
	326	Seq_EMBL _MTCY7H7Bc, Accession No. Z95557, May 20, 1997		
	327	Seq_EMBL _MTCY24G1, Accession No. Z83858, Jan. 13, 1997		
	328	Seq_EMBL _MTCY19G5, Accession No. Z77826, Jul. 31, 1996		
	329	Seq_EMBL _MTCY261, Accession No. Z97559, Jul. 10, 1997		
	330	Seq_EMBL _Z78020, XP002224823		

<b>Examiner Signature</b>	<b>Date Considered</b>
---------------------------	------------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

†Applicant's unique citation designation number (optional). ‡Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<b>Application Number</b>	09/724,685
		<b>Filing Date</b>	11-28-2000
		<b>First Named Inventor</b>	Steven G. Reed
		<b>Art Unit</b>	1645
		<b>Examiner Name</b>	Rodney P. Swartz
<b>(Use as many sheets as necessary)</b>	<b>Attorney Docket Number</b>	GSK006C13/CRX411C13	
Sheet	25	of	32

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	331	Seq_EMBL _ P41403, XP002224824	
	332	Seq_EMBL _ Q50596, XP002224822	
	333	Seq_EMBL _ Z17372, XP002224825	
	334	Seq_EMBL _ U90239, XP002224826	
	335	Seq_EMBL _ P97048, XP002224827	
	336	Seq_Accession_No_AU077540	
	337	Seq_EMBL _ P15712, (1990-04-01) "PBP-1 from M. tuberculosis" XP002359448	
	338	Seq_Uniprot _ Q79FV1	
	339	Seq_Uniprot _ O06267	
	340	Seq_Uniprot _ P96364	

Examiner Signature	Date Considered
-----------------------	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.